

# **United States Court of Appeals for the Federal Circuit**

*Appeal No.*  
03-1524  
(Serial No. 09/597,608)

**IN RE JOHN NGAI and DAVID LIN**

Richard Aron Osman, Science & Technology Law Group, of Hillsborough, California, for appellants.

John M. Whealan, Solicitor, United States Patent and Trademark Office, of Arlington, Virginia, for appellee. With him on the brief were Raymond T. Chen and Stephen Walsh, Associate Solicitors.

Appealed from:      United States Patent and Trademark Office  
                            Board of Patent Appeals and Interferences

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NONPRECEDENTIAL OPINION ISSUED: March 8, 2004  
PRECEDENTIAL OPINION ISSUED: May 13, 2004

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Before MICHEL, GAJARSA, and LINN, Circuit Judges.

PER CURIAM.

Petitioners John Ngai and David Lin (collectively "Ngai") appeal from the decision by the Board of Patent Appeals and Interferences ("Board") rejecting claim 19 of the petitioner's patent application No. 09/597,608 (the "608 application") as being anticipated by prior art. Ex parte Ngai, No. 2002-1092 (BPAI 2003); see 35 U.S.C. § 102(b). We find that the Board's decision is supported by substantial evidence and accordingly affirm.

## I. BACKGROUND

The study of nucleic acids, including ribonucleic acids ("RNA"), has a wide variety of applications in the field of biological sciences. Unfortunately, oftentimes the amount of RNA that experimenters can extract from the cells can be quite small. Experimenters

must duplicate the material many times over to assemble a quantity sufficient for experimentation. This process is called "amplification." Additionally, some RNA strands may be difficult to detect in cells. A process called "normalization" enhances experimenters' ability to detect the RNA that is expressed at low levels.

Ngai invented a new method for amplifying and normalizing RNA. He submitted the '608 application to patent this invention. The '608 application contained 20 claims. Claims 1-18 are drawn to a method of amplifying RNA. Claim 1 is representative of the method claims 1-18 and reads:

A method for normalizing and amplifying an RNA population comprising the steps of:  
copying the message RNA (mRNA) to form first single stranded (ss) cDNA;  
converting the first ss-cDNA to first double stranded (ds) cDNA;  
linearly amplifying the first ds-cDNA to form first amplified RNA (aRNA);  
tagging the 3' end of the first aRNA with a known sequence to form 3' tagged first aRNA;  
copying the 3'-tagged first aRNA to form second ss-cDNA; and  
normalizing the mRNA or the first aRNA.

Claim 19 is drawn to a kit designed to perform the method recited in Claim 1. Claim 19 reads:

A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides. (emphasis added).

Ngai does not dispute that prior art teaches a kit comprising instructions and a 10X buffer.<sup>1</sup>

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<sup>1</sup> Ngai also does not dispute that a 10X buffer is a type of buffer mentioned in proposed claim 19.

### Proceedings Below

The Examiner allowed claims 1-18 but rejected claims 19 and 20 as unpatentable, under 35 U.S.C. § 102(b) and 35 U.S.C. § 103 respectively. The Board reversed the rejection with respect to claim 20 and affirmed the rejection of claim 19 as anticipated by prior art.

The Board agreed with the Examiner that prior art anticipates claim 19 because it teaches each and every limitation of the claim including instructions and a buffer agent. The Board concluded that the only difference between the prior art and claim 19 is the content of the instructions. Finding that the content of the instructions was not "functionally related" to the kit, the Board concluded that claim 19 should be rejected as anticipated by prior art.

Ngai appealed the Board's decision to this Court. The only issue presented by this appeal is whether claim 19 should have been allowed. We have jurisdiction under 28 U.S.C. § 1295(a)(4).

### II. STANDARD OF REVIEW

Anticipation is a question of fact. In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). We review PTO's factual findings for substantial evidence. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000).

### III. DISCUSSION

Ngai argues that the addition of new printed matter to a known product makes the product patentable. He rests his argument on the fact that claim 19 is limited to kits containing instructions teaching the method described in claim 1. Ngai argues that because prior art does not teach a limitation of "instructions describing the method of

claim 1," combined with an amplification kit, the petitioner's claim cannot be anticipated. Ngai relies on the language of In re Gulack, 703 F.2d 1381 (Fed. Cir. 1983): "[The] [d]ifference between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter." Id. at 1385.

The PTO argues that Ngai's claim merely teaches a new use for an existing product. Thus, according to the PTO, Ngai can claim the new use as a method, but he cannot claim the existing product itself. The PTO relies on a different passage of Gulack and argues that in order to qualify under Gulack, the printed matter must be functionally related to the underlying object. "The critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate." Id. at 1386.

~~The dispute between Ngai and PTO reduces to the question of the proper meaning of Gulack. The PTO has the better argument. In Gulack, the Board rejected a claim directed to a circular band designed for mathematical and educational purposes. The invention consisted of "(1) a band, ring, or set of concentric rings; (2) a plurality of individual digits imprinted on the band or ring at regularly spaced intervals; and (3) an algorithm by which the appropriate digits are developed."~~ Id. at 1387. The rejection was premised upon the fact that a circular band with items printed upon it was well known in the art. See id. at 1384. We reversed, finding that the numbers printed on the band had a functional relationship to the band itself. The Court stated: "[t]he[] digits are related to the band in two ways: (1) the band supports the digits; and (2) there is an endless sequence of digits--each digit residing in a unique position with respect to every

other digit in an endless loop. Thus, the digits exploit the endless nature of the band.” Id. at 1386-87. Although the prior art disclosed a band with printed matter, the Court concluded that the prior art neither “disclose[d] nor suggest[ed] either feature” of Gulack’s invention. Id. at 1387.

This case, however, is dissimilar from Gulack. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for “educational and recreational mathematical” purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the Gulack court pointed out, “[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.” Id. If we were to adopt Ngai’s position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product. This was not envisioned by Gulack. Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product.

CONCLUSION

For the foregoing reasons, we find that the Board's decision is supported by substantial evidence, and accordingly affirm.

AFFIRMED

IV. COSTS

No costs.